

## U.S. and European Acceptance of Alternative Methods 1998-2009<sup>1</sup>

No.	Method	ICCVAM BRDs and Peer Review	U.S. Regulatory Acceptance/Endorsement	OECD/Other Adoption	EU Regulatory Acceptance/Endorsement <sup>2</sup>
1	CORROSITEX Skin Corrosivity Test	ICCVAM peer review and report; recommended in 1999	Yes, accepted by U.S. in 2000; as OECD TG 435 in 2006	OECD Test Guideline (TG) 435 (2006)	Yes, via OECD
2	Local Lymph Node Assay for skin sensitization	ICCVAM peer review and report; recommended in 1999	Yes, accepted by U.S. in 1999; as OECD TG 429 in 2002	OECD TG 429 (2002) ISO (2002)	Yes, via OECD
3	Up and Down Procedure (UDP)	ICCVAM peer review and report; recommended in 2001	Yes, accepted by U.S. in 2003; as OECD TG 425	OECD TG 425 (2001)	Yes, via OECD
4	Fixed Dose Procedure (FDP)	ICCVAM Working Group (WG) contributed to TG development	Yes, as OECD TG 420 in 2001	OECD TG 420 (2001)	Yes, via OECD
5	Acute Toxic Class Method (ATC)	ICCVAM WG contributed to TG development	Yes, as OECD TG 423 in 2001	OECD TG 423 (2001)	Yes, via OECD
6	EpiSkin Skin Corrosivity Test	ICCVAM review and report; recommended in 2002	Yes, as OECD TG 431 in 2004	OECD TG 431 (2004)	67/548/EEC
7	EpiDerm Skin Corrosivity Test	ICCVAM review and report; recommended in 2002	Yes, as OECD 431 in 2004	OECD TG 431 (2004)	67/548/EEC
8	SkinEthic Skin Corrosivity Test	ICCVAM contributed to U.S. OECD TG review	Yes, as OECD 431 in 2004	OECD 431 (2004)	Yes, via OECD
9	Rat TER Skin Corrosivity Test	ICCVAM review and report; recommended in 2002	Yes, as OECD TG 430 in 2004	OECD TG 430 (2004)	67/548/EEC
10	3T3 NRU Phototoxicity Test	ICCVAM contributed to U.S. OECD TG review	Yes, as OECD TG 432 in 2004	OECD TG 432 (2004)	67/548/EEC
11	3T3 NRU Phototoxicity Test: Application to UV Filter Chemicals	ICCVAM contributed to U.S. OECD TG review	Yes, as OECD TG 432 in 2004	OECD TG 432 (2004)	Yes, via OECD
12	<i>In vitro</i> dermal absorption methods	ICCVAM contributed to U.S. OECD TG review, expert consultation meetings	Yes, as OECD TG 428 in 2004	OECD TG 428 (2004)	Yes, via OECD
13	Use of Humane Endpoints in Animal Testing of Biological Products	ICCVAM agency initiative	Yes, 9 CFR 117.4e	NA	
14	Rabies Vaccine, Humane Endpoints	ICCVAM agency initiative	Yes, 9 CFR 117.4e	NA	
15	Bovine Corneal Opacity and Permeability (BCOP) Test Method	Yes, peer review and report; recommended in 2007	Yes, acceptance in 2008	<i>Draft TG approved, formal adoption June 2009</i>	<i>Draft TG approved, formal adoption June 2009</i>
16	Isolated Chicken Eye (ICE) Test Method	Yes, peer review and report; recommended in 2007	Yes, acceptance in 2008	<i>Draft TG approved, formal adoption June 2009</i>	<i>Draft TG approved, formal adoption June 2009</i>
17	Acute Toxicity <i>In Vitro</i> Starting Dose Procedure, 3T3 cells	Yes, 2001 workshop report; 2006 peer review and report; recommended in 2008	Yes	<i>OECD Guidance Document in preparation</i>	<i>OECD Guidance Document in preparation</i>

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18	Acute Toxicity <i>In Vitro</i> Starting Dose Procedure, NHK cells	Yes, 2001 workshop report; 2006 peer review and report; recommended in 2008	Yes	<i>OECD Guidance Document in preparation</i>	<i>OECD Guidance Document in preparation</i>
19	ELISA Test for Batch Potency Testing of Erysipelas Vaccines (refinement)	ICCVAM coordinated agency consideration	Yes, per 27 CFR 610.10; are reviewed on a case-by-case basis	NA	Published in European Pharmacopeia
20	Relevance of the Target Animal Safety Test for batch safety testing of vaccines for veterinary use	ICCVAM coordinated agency consideration	Yes, per 9 CFR 113.4	NA	Published in European Pharmacopeia
21	ELISA Test for Batch Potency Testing of Human Tetanus Vaccines refinement	ICCVAM coordinated agency consideration	Yes, per 27 CFR 610.10; are reviewed on a case-by-case basis	NA	Published in European Pharmacopeia
22	ToBI Test for Batch Potency Testing of Human Tetanus Vaccines refinement	ICCVAM coordinated agency consideration	Yes, per 27 CFR 610.10; are reviewed on a case-by-case basis	NA	Published in European Pharmacopeia
23	Human Whole Blood/Interleukin-1 $\beta$ <i>In Vitro</i> Pyrogen Test	ICCVAM peer review and report; recommended in 2008	<i>Sent to agencies October 2009; response due April 2009</i>	NA	
24	Human Whole Blood/Interleukin-1 $\beta$ <i>In Vitro</i> Pyrogen Test: Application of Cryopreserved Human Whole Blood	ICCVAM peer review and report; recommended in 2008	<i>Sent to agencies October 2009; response due April 2009</i>	NA	
25	Human Whole Blood/Interleukin-6 <i>In Vitro</i> Pyrogen Test	ICCVAM peer review and report; recommended in 2008	<i>Sent to agencies October 2009; response due April 2009</i>	NA	
26	Human Peripheral Blood Mononuclear Cell/Interleukin-6 <i>In Vitro</i> Pyrogen Test	ICCVAM peer review and report; recommended in 2008	<i>Sent to agencies October 2009; response due April 2009</i>	NA	
27	Monocytoid Cell Line Mono Mac 6/Interleukin-6 <i>In Vitro</i> Pyrogen Test	ICCVAM peer review and report; recommended in 2008	<i>Sent to agencies October 2009; response due April 2009</i>	NA	
<b>Totals</b>		<b>27</b>	<b>27</b>	<b>14</b>	<b>16</b>

<sup>1</sup>Updated May 4, 2009

<sup>2</sup>Information provided by Executive Secretary, ESAC (European Centre for the Validation of Alternative Methods Scientific Advisory Committee), April 13, 2008